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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/575,361 12/24/95 CHANDRASEGARAN S 213779

18M2/0516

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EXAMINER

PATTERSON, C

ART UNIT

PAPER NUMBER

1814

DATE MAILED:

05/16/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/6/97 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-26 are pending in the application.

Of the above, claims 1-8 are withdrawn from consideration.

2. ☐ Claims have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 9-26 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Applicant's election with traverse of claims 9-26 in Paper No. 7 is acknowledged. The traversal is on the grounds that "the inventions of Groups I and II are so linked as to form a single general inventive concept, and that it would not pose an undue burden on the Examiner to examine all of the pending claims". Additionally it is argued that "for inactivating a target DNA, one needs to engineer the DNA constructs, and then clone, purify and characterize the chimeric restriction enzymes" which are "the same steps necessary for cloning restriction endonucleases which could also be used to enzymatically inactivate target DNA".

This is not found persuasive because, to start with, Group II is limited to any "nuclease" while Group I is limited to "restriction endonucleases". Secondly, Group I involves a ligase, which is presumably necessary for the invention while Group II does not. Thirdly, the two groups are directed to entirely different processes, one to cloning a restriction endonuclease and the other to inactivating DNA. After carefully reading the specification it is not seen how these two processes relate. Group I is a method of cloning a restriction endonuclease wherein a ligase is engineered so as to express constitutively and using this to clone a restriction endonuclease, whereas Group II is a method of inactivating a DNA comprising introducing the gene for the endonuclease into a cell, inducing the cell to produce the endonuclease and thereby inactivating the DNA. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to teach how to make and/or use the claimed invention.

In the sentence spanning pages 34 and 35 it is stated that "BL21 (DE3) (pACYC *lig*) transformed at about 5-10 fold lower efficiency as compared to BL21 (DE3) cells (Figure 8)". In the second sentence in the next paragraph (lines 8-10 of page 35) it is stated that "BL21 (DE3) with pACYC *lig* transform about 2-fold better compared to BL21 (DE3) without pACYC *lig*". These two statements appear to be completely opposites of each other. One of ordinary skill in the art reading this disclosure would not know what the results of the tests

were and would not know how to practice the invention. Figure 8 and Table II appear to agree with these contradictory statements.

Other than a general stating of the subject matter of claims 9-26 in the specification, e.g. on page 9, line 9 through page 10, line 24, there is no enablement in the instant specification that would teach the ordinary artisan reading this specification to practice the subject matter of the instant claims. Most of the specification is devoted to a method of cloning using a ligase, which is the subject of claims 1-8 that were non-elected. Although it is maintained that it would have been obvious to practice the method of claims 9-26, as outlined in the prior art rejections *infra*, the specification does not teach this. Presuming for the sake of argument that there might be some problems, e.g. in placing a gene coding for a nuclease from a bacteria into a plant or animal cell and having it express, this is not addressed in the instant specification.

Claims 9-26 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of

this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 9, 12-14, 18 and 25-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wilson (A). The instant reference teaches in column 3, line 65 - column 4, line 33 the placing of a gene encoding a nuclease into a plasmid, delivering the plasmid into cells and inactivation of non-methylase clones by the endonuclease after expression.

Claims 9-20 and 22-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Wilson (A). The reference is characterized *supra*. It would have been obvious to one of ordinary skill in the art to deliver the gene coding for the nuclease by liposomes, integrate it into the chromosome, use a hybrid or other "non-natural" restriction endonuclease or to place the gene into mammalian or plant cells, ab-

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sent convincing to the contrary. Essentially what applicant is claiming is placing a gene encoding a nuclease into some cell, having the gene produce the nuclease and then having the nuclease "inactivate" the DNA of the cell by digesting it. It is maintained that this would have been obvious given the level of knowledge in the art and well within the skill level of the ordinary artisan. Claim 21 has not been rejected because it is limited to hybrid restriction endonucleases that were designed and produced by applicant and the examiner has been unable to find them in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., Ph.D. whose telephone number is (703) 308-1834. The examiner can normally be reached on any day of the week from 7:30 AM until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax, can be reached on (703) 308-4216. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patterson
May 5, 1997


CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800